

Remarks

Claims 1-9, 11-14, 18, 19, 21, 36, 39 and 41-56 are pending. In the present action, the Examiner has rejected claims 1-9, 11-14, 18, 19, 21, 36, 39 and 41-56 as allegedly obvious under 35 U.S.C. §103(a) from US 2002/0103527 to Kocur et al. (hereinafter “Kocur”) in view of WO 99/39662 to Chobotov (hereinafter “Chobotov”) and US 6,051,648 to Rhee et al. (hereinafter “Rhee”). Applicants respectfully request reconsideration in light of the following arguments.

Kocur is directed to a stent having a pocket for containing and delivering a biological agent. Chobotov is directed to an endovascular graft having, *inter alia*, inflatable cuffs and channel(s).

Kocur teaches that a therapeutic agent may be used within a channel of fold of its graft. As acknowledged by the Examiner, Kocur fails to disclose, teach or suggest the use of a an inflation medium which includes a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer, as set forth in independent claims 1, 21, and 39 of the subject application. Thus, Kocur is completely silent as to an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer may be useful for delivery of its therapeutic agent through the wall of its graft to the tissue of a bodily lumen as set forth in independent claims 1, 21, and 39.

The Examiner looks to Rhee to cure the deficiencies of Kocur, alleging that “Rhee et al demonstrates the use of host polymer (polyethylene glycol, a curable liquid) for containing bioactive material(s) in conjunction with a graft”, citing Col. 18, line 21. Applicant respectfully asserts that the Examiner’s construction of Rhee is improper as it picks and chooses from the disclosure to support Examiner’s own allegations while ignoring the actual disclosure and primary purpose of the Rhee. The portion of text to which the Examiner refers is under the heading of “Use of the Crosslinked Synthetic Polymers as Bioadhesives”. (Col. 16, lines 56-57).

Rhee defines the terms “bioadhesive” and biological adhesive”, and “surgical adhesives” as interchangeable terms to “refer to biocompatible compositions capable of

effecting temporary or permanent attachment between the surfaces of two native tissues, or between a native tissue surface and a non-native tissue surface or surface or a surface of a synthetic implant.” (Col. 16, lines 62-67, emphasis added). The bioadhesive can be used between:

- (1) two native tissues;
- (2) a native tissue surface and a non-native tissue surface; and
- (3) a native tissue surface and a surface of a synthetic implant.

Looking within the same discussion, there is further support to the assertion that the Examiner has improperly construed Rhee, as it provides, at least one of the first and second surfaces is “a native tissue surface” while “[t]he other surface may be a native tissue surface, a non-native tissue surface, or a surface of a synthetic implant.” (Col. 17, lines 60-61, Col. 18, lines 5-6). Rhee defines a synthetic implant as “grafts, stents, and stent/graf [sic] combinations” (Col. 18, lines 20-21). Thus, Rhee discloses the use of two cross-linked synthetic polymers to adhere a native tissue to a native tissue, a non-native tissue, or a synthetic implant. Thus, Rhee specifically requires that its cross-linking polymer containing a bioactive substance must contact a native tissue surface. (Rhee, column 17, lines 60-61). It should be noted that Rhee is silent as to using biological agents when adhering a native tissue to a second surface. There is absolutely no teaching, suggestion, or motivation in Rhee to use an inflation medium which includes a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer in a graft, or that Rhee’s compositions may be used within the inflatable channel of the present invention as set forth in independent claims 1, 21, and 39 of the subject application. Thus, Rhee fails to remedy the deficiencies of Kocur. Therefore, claims 1, 21, 39, and the claims which depend therefrom are patentably distinct and are not obvious in view of Kocur, Chobotov, and Rhee, taken individually and in combination thereof.

For the reasons above and those previously presented, clearly the disclosures of Kocur, Chobotov and Rhee do not provide sufficient predictability or expectation to support a *prima*

facie case of obviousness as none of these references, individually or in combination, disclose, teach or suggest the use of an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer within an inflatable porous channel of a graft.

In reference to Rhee, the Examiner incorrectly alleges that as Applicant has failed to address the Examiner's argument cited with respect to "Official Notice", and further alleges that the Rhee reference is now admitted prior art. In the previous action, the Examiner cited Rhee as documentary evidence, not official notice. Citing a reference as documentary evidence of an assertion is the clearly not "official notice". Official notice is where, in certain circumstances, an Examiner may "state facts not in the record or rely on common knowledge in making a rejection", where such "notice of facts [is done] without supporting documentary evidence" or reference. MPEP §2144.03 (internal marks omitted). When an Examiner provides a citation for an assertion, Applicant respectfully asserts that this is clearly not "official notice".

In relying on Rhee in furtherance of the Examiner's rejection, the Examiner did not use "official notice"; but rather, used "documentary evidence". Applicant fully traversed Examiner's interpretation of Rhee in the response to office action filed on January 29, 2009, alleging, *inter alia*, that Rhee was improperly combined with Chobotov and Kocur in the Examiner's alleged §103 references, and that the Examiner failed to state a *prima facie* obviousness case, in favor of the rejections being withdrawn. Thus, Applicant did address the Examiner's allegation of the disclosures of Rhee.

The Examiner alleged that Applicant did not address the "official notice" taken in the office action response of January 29, 2009 and thus, further alleged that the Examiner's reasoning is admitted prior art. This is impermissible and is clearly not the case. For the reasons set forth above, Applicant did challenge the Examiner's characterization of Rhee and specifically addressed the deficiencies of Rhee in the previous response. Applicant's arguments were directed, *inter alia*, to respectfully traversing the Examiner's incorrect assertion that "Rhee demonstrates the use of host polymer ... for containing bioactive material(s) in conjunction with a graft." The traversal with supporting arguments of the Examiner's incorrect interpretation of

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Rhee further refutes any reasoning the Examiner used to combine Rhee with Kocur and Chobotov and compounds the deficiencies of these references as applied to claims 1, 21, and 39 of the present invention.

Assuming *arguendo*, the Examiner did cite Rhee as “official notice”, before the Examiner’s official notice can be made admitted prior art against Applicant, the Examiner is required to include an explanation as to why the traversal of official notice was inadequate. MPEP §2144.03(c). No such explanation was included as the Examiner merely impermissibly concluded that “official notice was not addressed”.

Thus, Applicant respectfully traverses the Examiner’s statements with respect to Rhee being admitted prior art to the present invention and Applicant respectfully requests clarification of the record regarding the same. At the present case, the Examiner has incorrectly referenced and alleged “documentary evidence” as “official notice”. As Examiner’s previous assertion was not done through “official notice” and as Applicant has not made any express statement during prosecution identifying Rhee as “prior art” to the present application, Rhee is clearly not admitted prior art. Such a characterization is improper and is in direct conflict with the Manual of Patent Examining Procedure. MPEP §706.02(III), MPEP §2129 (I). As such, Applicant respectfully requests that this reference and statements made in reference to its disclosures be immediately withdrawn in order to correct and clarify the record.

Thus, independent claims 1, 21 and 39, and the claims which depend therefrom, are patentably distinct over Kocur, Chobotov and Rhee, taken individually or in combination. Therefore, withdrawal of the obviousness rejections of these claims is respectfully requested. Applicants respectfully submit that independent claims 1, 21 and 39, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

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Respectfully submitted,

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